UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,760	11/20/2003	Sachiko Kuno	9694-000006	8794

27572 7590 03/12/2009

HARNESS, DICKEY & PIERCE, P.L.C.
P.O. BOX 828
BLOOMFIELD HILLS, MI 48303

EXAMINER	
CARTER, CANDICE D	

ART UNIT	PAPER NUMBER
3629	

MAIL DATE	DELIVERY MODE
03/12/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/717,760	KUNO, SACHIKO	
	Examiner	Art Unit	
	CANDICE D. CARTER	3629	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-7 and 23-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-7 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Following is a Final Office Action in response to communications received on December 23, 2008. Claims 1, 2, and 5-7 have been amended. Claims 4, and 8-22 have been cancelled. Claims 23-25 have been added. Therefore, claims 1, 2, 5-7, and 23-25 are pending and have been addressed below.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1-3, 5-7, and 23-25 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Examiner contends that a process must be (1) tied to another statutory class (such as a particular machine) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing.

Claims 1-3, 5-7, and 23-25 are directed towards a method of doing business among two or more entities engaged in clinical trials and development of a pharmaceutical product comprising developing a product, obtaining clinical trial results, storing data, and providing a territorial distribution.

An applicant may show that a process claim satisfies 35 U.S.C. § 101 either by showing that his claim is tied to a particular machine, or by showing that his claim transforms an article. See Benson, 409 U.S. at 70. Certain considerations are applicable to analysis under either branch. First, the use of a specific machine or transformation of an article must impose meaningful limits on the claim's scope to

impart patent eligibility. See Benson, 409 U.S. at 71-72. Second, the involvement of the machine or transformation in the claimed process must not merely be insignificant extra-solution activity. See Flook, 437 U.S. at 590. *In re Bilski.*

In the instant case, the machine involvement recited in claim 1 is considered to be merely insignificant extra-solution activity, and as such, does not constitute statutory subject matter.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. **Claims 1-3, 5-7, and 23-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.**

Claims 1 and 25 mention transforming clinical trial results to regulatory data and transforming regulatory data to regulatory data that complies with the regulatory requirements of the secondary territory. The specification does not provide a sufficient explanation for the idea of transforming clinical trial results and regulatory data. This concept is not necessitated by the prior art and a person of ordinary skill in the art would be unable to complete this step as it is recited.

6. Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitations "transforming said clinical trial results to regulatory data" and "transforming regulatory data to regulatory data that complies with the regulatory requirements of the second territory" recited in claims 1 and 25, respectively was not included in the originally filed application and is considered to be new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 25 recites the limitation "transforming said clinical trial results to regulatory data" and "transforming regulatory data to regulatory data that complies with the regulatory requirements of the second territory". It is unclear what Applicant means by these limitations in these claims. Examiner is unsure what it means to transform clinical results into regulatory data or regulatory data into regulatory data that complies with the regulatory requirements of the second territory. Appropriate clarification is requested.

Claim 1 also recites the limitation "said electronic database representing a market for regulatory data and information relating to the pharmaceutical product". It is unclear what Applicant means by the limitation in this claim. Examiner is unsure how a database represents a market. Appropriate clarification is requested.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-3, 5-7, and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bleicher et al. (6,820,235, hereafter Bleicher) in view of PR Newswire (2000) and further in view of Nutter et al. (20030061133, hereafter Nutter).

As per claim 1, Bleicher discloses a method of doing business among two or more entities engaged in clinical trials and development of a pharmaceutical product, said method comprising:

developing the pharmaceutical product having physical characteristics and conducting clinical trials by administering said pharmaceutical product to human trial subjects (col. 1, line 16-31 discloses developing a drug and conducting clinical trials on patients)

Obtaining clinical trial results from said clinical trials wherein the clinical trial results relate to observed results of administering said pharmaceutical product to human trial subjects (col. 1, line 25-col. 2, line 7 discloses collecting clinical data from the trials of the drug performed on human patients).

Storing said regulatory data and information on an electronic regulatory data database residing on the memory of a computing device, wherein the information to the physical characteristics of the pharmaceutical product (col. 6, line 6-15 discloses storing clinical trial data in a database and col. 9, line 8-13 discloses maintaining regulatory documents).

Furthermore, Examiner considers the specific information stored in the database to be nonfunctional descriptive material. The specific type of information that is stored in the database does not change the function of the claimed invention. Examiner asserts that the database of Bleicher is fully capable of storing any type of information.

Bleicher, however, fails to explicitly disclose the pharmaceutical product is the subject of a multinational patent portfolio; providing a territorial distribution of at least some of the rights under said patent portfolio from a first party having rights in the multinational patent portfolio and the regulatory data and information to a second party;

PR Newswire discloses licensing agreements in pharmaceutical products (abstract discloses Cortex pharmaceutical company licenses out rights in order to enable Servier to develop and commercialize Cortex's technology and research for their own research within Cortex's territory).

Therefore it would have been obvious to one of ordinary skill in the pertinent art at the time the invention was made to modify the clinical trial data management of Bleicher to include the licensing agreements as taught by PR Newswire in order to offset some of the clinical costs of research

Nutter discloses an intellectual property licensing program providing a territorial distribution of at least some of the rights under said patent portfolio (¶ 19 and 20 discloses a selling entity having an IP asset that is a portfolio of patents and selling it to an investment entity and ¶ 23 discloses the IP investment entity licensing out the right to use the IP in a defined geographic territory)

Therefore, it would have been obvious to one of ordinary skill in the pertinent art at the time the invention was made to modify the clinical trial data of the Bleicher and PR newswire combination to include the patent portfolio of Nutter in order to obtain funds with may be applied against start up costs associated with patent management.

The Bleicher, PR Newswire, and Nutter combination fails to explicitly disclose providing access to said electronic regulatory database by the first party over a communications network to the second party, said electronic database representing a market for regulatory data and information relating to the pharmaceutical product subject of the multinational patent portfolio and obtained in the first party's clinical trials and development whereby said regulatory data and information can be used by the second party in a second territory for purposes of obtaining regulatory approval to market the pharmaceutical product in the second territory; and using animal trial subjects.

It would have been obvious to one of ordinary skill in the pertinent art at the time the invention was made to modify clinical trial data management of the Bleicher, PR Newswire, and Nutter combination to include providing access to said electronic regulatory database to the second party whereby said regulatory data and information can be used by the second party in a second territory for purposes of obtaining regulatory approval to market the pharmaceutical product in the second territory because it is old and well known that upon entering into a partnership with another company that they are granted access to some or all of the information obtained by the other company.

It would have been obvious to one of ordinary skill in the pertinent art at the time the invention was made to modify the clinical trial data management of the Bleicher, PR Newswire, and Nutter combination to include using animal trial subjects because it is old and well known to use animal trial subjects in clinical research.

Furthermore, Examiner considers the fact that the portfolio is a multinational portfolio to be nonfunctional descriptive material because it does not change the function of the claimed invention. Examiner asserts that the invention would perform the same way regardless of whether the portfolio is multinational or not.

As per claim 2, the Bleicher and PR Newswire combination fails to explicitly disclose secondary market comprises granting certain territorial rights the first party's regulatory data and information for an amount compensation that relates to the first party's cost of development.

As per claim 2, Nutter discloses "wherein said secondary market comprises granting certain territorial rights in a party's regulatory data and information for an amount compensation relates to the first party's cost of development" (¶ 20 discloses obtaining funds from the sale of IP assets to apply to start up costs, where start up costs are costs of development).

Therefore, it would have been obvious to one of ordinary skill in the pertinent art at the time the invention was made to modify the Bleicher and PR Newswire combination to include obtaining compensation that relates to the first party's cost of development as taught by Nutter in order to cover the cost of development with the compensation from the granting of territorial rights.

As per claim 3, Nutter further discloses "wherein said compensation comprises royalty payments, the rate of which are proportional the commercial advantage conferred on the second party when the regulatory data and information is obtained" (¶ 23 discloses royalty payments to the seller that is a periodic payment of a percentage of revenues, where a percentage is a proportion).

Therefore, it would have been obvious to one of ordinary skill in the pertinent art at the time the invention was made to modify the Bleicher and PR Newswire combination to include royalty payments in order to cover the cost of development with the payments from the granting of territorial rights.

As per claim 5, The Bleicher and PR Newswire combination discloses all of the elements of the claimed invention but fails to explicitly disclose the territorial distribution of rights is provided by an exclusive territorial license.

Nutter discloses "wherein the territorial distribution of rights is provided by an exclusive territorial license" (¶ 23 discloses licensing rights to use the IP in a defined territory).

Therefore, it would have been obvious to one of ordinary skill in the pertinent art at the time the invention was made to modify the Bleicher and PR Newswire combination to include the exclusive territorial license as taught by Nutter in order to allocate risk and reward flexibly to meet the needs of a particular application.

As per claims 6 and 7, The Bleicher and PR Newswire combination discloses all of the elements of the claimed invention but fails to explicitly disclose the parties are independent entities.

Nutter further discloses "wherein the parties are independent entities"; and "at least three parties" (Fig. 1 and ¶ 18 discloses independent entities and ovals that represent the entities involved, where there are 4 ovals that represent the different entities).

Therefore, it would have been obvious to one of ordinary skill in the pertinent art at the time the invention was made to modify the Bleicher and PR newswire combination to include the independent parties because such partnerships/agreements/arrangements, typically, are between independent entities.

As per claims 23 and 24, The Bleicher, PR newswire, and Nutter combination discloses all of the elements of the claimed invention but fails to explicitly disclose providing a territorial distribution further comprises licensing and selling the patent rights

along with the regulatory data from the first party to the second party that is a licensing party.

It would have been obvious to one of ordinary skill in the pertinent art at the time the invention was made to modify the Bleicher, PR newswire, and Nutter combination to include licensing the patent rights along with the regulatory data from the first party to the second party that is a licensing party because it is old and well known that upon entering into a partnership with another company that they are granted access to all of the information obtained by the other company.

As per claim 25, Bleicher discloses, as best understood, transforming the regulatory data to regulatory data that complies with the regulatory requirements (col. 1, line 39-40 discloses obtaining regulatory approval, where in order to gain approval you must have regulatory data that complies with requirements).

Bleicher fails to explicitly disclose a second territory.

PR Newswire discloses a second territory (abstract discloses Cortex pharmaceutical company licenses out rights in order to enable Servier to develop and commercialize Cortex's technology and research for their own research within Cortex's territory).

Therefore it would have been obvious to one of ordinary skill in the pertinent art at the time the invention was made to modify the clinical trial data management of Bleicher to include the licensing agreements as taught by PR Newswire in order to offset some of the clinical costs of research.

Response to Arguments

10. Applicant's arguments filed December 23, 2008 have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the two parties in PR Newswire are engaged in a partnership as opposed to a seller/buyer relationship) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant's arguments with respect to claim 1 has been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CANDICE D. CARTER whose telephone number is (571) 270-5105. The examiner can normally be reached on Monday thru Thursday 7:30am- 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Weiss can be reached on (571) 272-6812. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. D. C./
Examiner, Art Unit 3629

/JOHN G WEISS/
Supervisory Patent Examiner, Art Unit 3629